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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,879

10/27/2005

Bengt Guss

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

07/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/530,879	Applicant(s) GUSS ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10,12,13,15-19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10,12,13,15-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/25/2008</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

Applicant's amendment and remarks filed on 4/15/2009 are acknowledged. Claims 1-5, 7, 12-13, 15, and 19 are amended. Claim 20 is cancelled.

Based on applicant's amendment, claims 2, 4-5, 7-8, 10, 12-13, 15-18, and 21 are no longer withdrawn.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I, II, III, IV, and VI, as set forth in the Office action mailed on 12/26/2007 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-5, 7-8, 10, 12-13, 15-19, and 21-22 are pending. Claims 19 and 22 are withdrawn as being drawn to nonelected inventions. Claims 1-5, 7-8, 10, 12-13, 15-18, and 21 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 11/25/2008 has been considered. An initialed copy is enclosed. The information disclosure statement originally filed on 11/28/2005 (a copy of which was resubmitted on 11/25/2008) was previously considered and an initialed copy was previously sent to applicant.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on pages 14 and 19-20. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1645

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of embedded hyperlink and/or other form of browser-executable code.

The use of the trademark TWEEN has been noted in this application on pages 18 and 22. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claims 2 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections Withdrawn

The rejection of claims 1, 3, and 20 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in light of applicant's amendment thereto.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn. The cancellation of the claim renders the rejection moot.

The rejection of claims 1, 3, and 20 under 35 U.S.C. 102(b) as being anticipated by Lindmark *et al.* (Res. Vet. Sci., 66:93-99, 1999, IDS filed 6/22/2005), is withdrawn in light of applicant's amendment thereto.

Art Unit: 1645

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8, 10, 12-13, 16-18, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn vaccine compositions comprising a portion of the *S. equi equi* proteins EAG (SEQ ID NO:1), SEC (SEQ ID NO:22), and Sc1C (SEQ ID NO:27). The claims also include methods of producing said vaccine as well as methods of treatment and prophylaxis in non-human animals against *S. equi* infection. The claims encompass prevention of infection caused by the three subspecies of *S. equi*; *equi*, *zooepidemicus*, and *ruminatorum*.

The specification discloses examples where various combinations of polypeptides from *S. equi equi* were administered to mice, followed by challenge with *S. equi equi*. Each composition included E. coli Heat-Labile Enterotoxin Subunit B (EtxB) as an adjuvant. The combinations used were FNZN, SFSC1, EA4GB (SEQ ID NO:13, 10, and 1) and FNZN, SFSC1, EA4GB, SEC2.16 (13, 10, 1, and 20). EA4GB (SEQ ID NO:1) with adjuvant was also administered in one example. The compositions induced an antibody response; however, none of the compositions was capable of preventing infection, instead, the bacterial load and weight loss were merely reduced.

The specification lacks any description of a composition or method that elicits protective immunity, and in fact, shows that the compositions were incapable of inducing such immunity.

Therefore, the specification provides insufficient written description to support the genus encompassed by the claims. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification

Art Unit: 1645

does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only methods of treatment of *S. equi* infection, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115).

Claims 7-8, 10, 12-13, 16-18, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic compositions and methods of therapeutic treatment of *S. equi*, does not reasonably provide enablement for vaccines or methods of prophylaxis against *S. equi*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Art Unit: 1645

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn vaccine compositions comprising a portion of the *S. equi equi* proteins EAG (SEQ ID NO:1), SEC (SEQ ID NO:22), and Sc1C (SEQ ID NO:27). The claims also include methods of producing said vaccine as well as methods of treatment and prophylaxis in non-human animals against *S. equi* infection.

Breadth of the claims: The claims encompass prevention of infection caused by the three subspecies of *S. equi*; *equi*, *zooepidemicus*, and *ruminatorum*.

Guidance of the specification/The existence of working examples: The specification discloses examples where various combinations of polypeptides from *S. equi equi* were administered to mice, followed by challenge with *S. equi equi*. Each composition included E. coli Heat-Labile Enterotoxin Subunit B (EtxB) as an adjuvant. The combinations used were FNZN, SFSC1, EA4GB (SEQ ID NO:13, 10, and 1) and FNZN, SFSC1, EA4GB, SEC2.16 (13, 10, 1, and 20). EA4GB (SEQ ID NO:1) with adjuvant was also administered in one example. The compositions induced an antibody response; however, none of the compositions was capable

Art Unit: 1645

of preventing infection, instead, the bacterial load and weight loss were merely reduced.

State of the art: Post-filing art shows results similar to that disclosed in the specification. For example, Flock *et al.* (Vaccine, 24:4144-4151, 2006; IDS filed 11/25/2008) showed the results of challenge experiments using various combinations of EAG, CNE (SEC), Sc1C, SFS, and FNZ. Flock also found that the bacterial load was reduced but that prevention of infection did not occur.

There is no demonstration of protective immunity using any of the claimed compositions, and in fact, it was shown that the compositions were incapable of inducing such immunity. Therefore, in view of the lack of support in the art and specification, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine or prophylaxis method as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-8, 10, 12-13, 15-18, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, and 4 are vague and indefinite because SEQ ID NO:22 must be a fragment of SEQ ID NO:4 and SEQ ID NO:27 must be a fragment of SEQ ID NO:23. However, examination of these sequences reveals that SEQ ID NO:22 is not a fragment of SEQ ID NO:4 and SEQ ID NO:27 is not a fragment of SEQ ID NO:23.

Applicant argues that SEQ ID NO:27 and SEQ ID NO:23 are referred to in the specification on pages 20-21 and that it is evident that SEQ ID NO:27 is a fragment of SEQ ID NO:23.

Applicant's arguments have been fully considered and deemed non-persuasive.

Examination of the sequences clearly shows that SEQ ID NO:27 has amino acids that are not found in SEQ ID NO:23; therefore, it is clearly not a fragment of SEQ ID NO:23.

Art Unit: 1645

Claim 3 is vague and indefinite because SEQ ID NO:20 must be a fragment of SEQ ID NO:4. However, examination of this sequence reveals that SEQ ID NO:20 is not a fragment of SEQ ID NO:4.

Claim 5 is vague and indefinite because SEQ ID NO:13 must be a fragment of SEQ ID NO:2 and SEQ ID NO:10 must be a fragment of SEQ ID NO:3. However, examination of these sequences reveals that SEQ ID NO:13 is not a fragment of SEQ ID NO:2 and SEQ ID NO:10 is not a fragment of SEQ ID NO:3.

Regarding claim 16, the term "suitably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645